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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,633

06/09/2006

Todd Maibach

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,633	Applicant(s) MAIBACH, TODD	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-104 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20-35 and 37-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 18, 19 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3-28-06; 6-14-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response to election dated 3-4-10 and IDS dated 3-28-06 is acknowledged.

Election/Restrictions

1. Applicant's election with traverse of a) a consumable film containing nitroglycerin, water soluble polymer and a pharmaceutical agent; and b) the pharmaceutical agent is anti-hypertension and cardiovascular treatment agents. Such elections read on claims 18-19 and 36 in the reply filed on 3-4-10 is acknowledged. The traversal is on the ground(s) that if the search and examination of all the claims in an application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to independent or distinct inventions. It is argued that in order for an Election to Species to be proper, the examiner is required to show "there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required." MPEP § 808.01 (a). Applicants respectfully submit that searching these inventions together will pose no additional burden on the Examiner. In light of the foregoing, Applicants respectfully request reconsideration and withdrawal of the present election of species requirements. This is not found persuasive because the instant application claims a number of classes of active agents, which are different from each other in structure as well as in function. Further, a reference teaching an edible film comprising water soluble polymer and a therapeutic agent does not render an edible film with water soluble polymer, nitroglycerine and a therapeutic agent. For instance, Leung et al, US 2003/0206941, only teaches an edible film with water soluble polymer with a therapeutic agent but not

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an edible film with water soluble polymer, nitroglycerine and a therapeutic agent. Thus, there the reference of Leung lacks the special technical feature. Hence, the requirement is still deemed proper and is therefore made FINAL.

Claims 18-19 and 36 read on the claimed species and are examined in this action.

Claims 1-17, 20-35 and 37-104 have been withdrawn as being non-elected.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4764378 to Keith in view of US 6596298 to Leung et al and US 6139847 to Chobanian et al OR Leung et al in view of Keith and Chobanian et al.

Claims 18-19 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4764378 to Keith in view of US 2007/0184093 to Hang and combination treatment nitroglycerin ace inhibitors or Hang in view of Keith and Chobanian et al.

Keith teaches buccal administration of drugs in an erodible matrix comprising polyethylene glycol, polyvinylpyrrolidone and a drug dispersed in a matrix (col. 2). Keith teaches that any drug can be incorporated in the matrix and in particular drugs treating cardiovascular conditions (col. 5, example 4). Claim 15 of Keith is directed to an embodiment containing nitroglycerin. Keith lacks the instant polymer pullulan.

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Leung et al. teach edible films that preferably include pullulan, antimicrobially effective amounts of thymol, methyl salicylate, eucalyptol, menthol; and contain pharmaceutical actives (Abstract, col. 2 summary of the invention). The film more preferably comprises pullulan as a film forming agent in amounts of 45% to 70% (col. 5, L 1-10, col. 11 and examples in col. 17-18) and further Leung suggests incorporating a number of medicaments or pharmacological agents (col. 12).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ pullulan polymer of Leung in the buccal matrix of Keith because Leung teaches that the films made of polymers such as pullulan, polyethylene glycol, cellulose etc., rapidly adhere to and also rapidly dissolve in the mouth of the consumer thus delivering the active agent quickly. Thus, Leung suggests equivalency of the polyethylene glycol of Keith and pullulan. A skilled artisan would be able to substitute PEG of Keith with pullulan of Leung and still expect the same function i.e., rapid dissolution in the mouth of the consumer so as to release the desired agent rapidly.

Alternatively, a skilled artisan would have employed cardiovascular protective agents such as nitroglycerin and others taught by Keith in the film containing polymers such as pullulan of Leung with an expectation to provide therapeutic or protective effects for cardiovascular conditions because Leung teaches that any pharmacological agent and Keith teaches instant claimed nitroglycerin and other cardiovascular agents as suitable medicaments for administering as oral or buccal films. A skilled artisan would have been able to employ combinations of medicaments for treating

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cardiovascular conditions with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4).

Hang teaches soluble films comprising a soluble polymer and a strengthening polymer (0017) for delivery of emergency medical care active agents such as nitroglycerin (0019). For the soluble films, Hang preferably teaches pullulan (0030). Hang does not teach an embodiment containing nitroglycerin and lacks the combination of nitroglycerin with other cardiovascular agents.

The teachings of Keith and Chobanian are discussed above. It would have been obvious for one of ordinary skill in the art at the time of the instant invention was made to employ pullulan polymer of Hang in the buccal matrix of Keith because Hang teaches that the films made of polymers such as pullulan rapidly dissolve in the mouth thus delivering the active agent quickly. A skilled artisan would be able to substitute PEG of Keith with pullulan of Hang and still expect the same function i.e., rapid dissolution in the mouth of the consumer so as to release the desired agent rapidly.

Alternatively, a skilled artisan would have employed cardiovascular protective agents such as nitroglycerin and others taught by Keith in the film containing polymers such as pullulan of Hang with an expectation to provide therapeutic or protective effects for cardiovascular conditions because Leung teaches that any pharmacological agent and Keith teaches instant claimed nitroglycerin and other cardiovascular agents as suitable medicaments for administering as oral or buccal films. A skilled artisan would have been able to employ combinations of medicaments for treating cardiovascular

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conditions with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 29, 2010

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